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EXAMINER

MOORE, WALTER A

ART UNIT

PAPER NUMBER

1783

NOTIFICATION DATE

DELIVERY MODE

09/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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RESPONSE TO AMENDMENT

Status of Claims

1. Claims 1, 3, 5-6, 10, 15, 17, 21-27 are pending. Claim 1 was amended, and claims 21-27 were added in the response filed on 9/2/2010. Claims 2, 4, 7-9, 11-14, 16, 18-19, and 20 were previously canceled.

Withdrawn Rejections

2. The objection to claim 1, made of record in the office action mailed on 6/24/2010, has been withdrawn due to applicant's amendment filed on 9/2/2010.

REJECTIONS

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 depends from claim 21, claim 21 recites tocopherol. Claim 22 recites tocopherol or tocotrienol. Therefore, the selection of tocopherol does not further limit claim 21.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The tocopherol weight ratio of 0.85 to 1.2 relative to the net weight of the yolk (claim 21, ln. 7-8) cannot be achieved as the invention is claimed and disclosed. To calculate the maximum weight ratio of the invention as claimed, insert the maximum claimed value of antioxidant (3,000 ppm) and the least amount of yolk (10%). Additionally, include the maximum disclosed weight of oil (80%, Specification, p. 14, first full paragraph). That calculation results in a weight ratio of 0.024 (calculation: $[3,000 \text{ ppm} * .80 \text{ oil}] / 0.10 \text{ yolk} = 0.024$). In the alternative, if the antioxidant is dispersed in both the water and oil phases then the maximum weight ratio of the antioxidant to the yolk is 0.027 (calculation: $[3000 \text{ ppm} * 0.90 \text{ (max disclosed water and oil)}] / 0.10 \text{ (yolk)} = 0.027$). Therefore, a weight ratio of 0.85 to 1.2 cannot be achieved in the invention as disclosed and claimed.

Please note the value of 90% indicating the amount of oil and water is derived from the concept that if the yolk was 10% of the composition, the oil and water would comprise the remaining 90% of the composition. The simplification does leave the antioxidant out of the composition. However, ignoring the amount of antioxidant only increases the value of the weight

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ratio. Therefore, discounting the weight of the antioxidant in the composition construes the claims in the light most favorable to the Applicant.

This rejection can be overcome by amending the claim to recite that the weight ratio is a percent by weight. Note this rejection is similar to the 35 USC 112 rejection made in the office action mailed on 7/7/2009. In response to the 7/7/09 action, Applicant amended the claims adding the phrase “percent by weight” after the ratio. Furthermore, Applicant amended the Specification to correct the omission.

7. Claims 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The weight ratio of 0.85 to 1.2 is indefinite as claimed. As discussed above, the weight ratio in amended Table 1 filed on 11/9/2009 is a percentage. Based on the presently claimed invention, the maximum weight ratio is 0.024. The calculation is based on the maximum values for the claimed amount of antioxidant (3000 ppm), the disclosed maximum percent of oil (80%, Specification, p. 14, first full paragraph), and the least claimed amount of yolk (10%, claim 21). The calculation results in a weight ratio of 0.024 (calculation: $[3000 \text{ ppm} * .8]/0.1 = 0.024$). A weight ratio of 0.024 is an order of magnitude smaller than the presently claimed ratio.

Furthermore, the minimum claimed weight ratio of 0.85 cannot be achieved until 2833% of the composition is oil. Calculation: $[3000 \text{ ppm} * \text{percent of oil}]/\text{percent of yolk} = .85$; $[3000/1000000 * \text{percent oil}]/10\% \text{ yolk} = .85$; $(.85 * .10 * 1000000)/3000 = 2833\%$.

As discussed above, the weight ratio appears to be a percent by weight, not a straight ratio. Therefore, for the purposes of examination the value will be interpreted as a percent.

Claim 21 is indefinite because the meaning of the phrase “an enzyme treated yolk as 10 to 15% in terms of liquid yolk” (claim 21, ln. 3) is unclear. It is unclear whether the limitation is claiming an amount of yolk in the composition or whether the limitation is claiming 10 to 15% of the yolk is enzyme treated. For the purposes of examination, the phrase is being interpreted as an amount of yolk in the composition. This interpretation is consistent with the disclosure that the yolk content of the composition is between 10 to 15% (Specification, p. 8, 2nd paragraph).

Claim 22 recites the limitation "the antioxidant" in line 2. Claim 22 depends from claim 21. Neither claim establishes an antioxidant. There is insufficient antecedent basis for this limitation in the claim. Examiner notes claim recites tocopherol, which is an antioxidant. However, tocotrienol is not a tocopherol. They are two different molecules.

Claim Rejections - 35 USC § 103

8. Claims 1, 3, 5, 10, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiiba et al., USPA 2002/0119239, in view of Goto et al., USPN 6,139,897.

Regarding claims 1, 21, and 22, Shiiba discloses an acidic oil-in-water emulsified composition (p. 1, para 0002). Shiiba discloses the composition includes fats and oils comprising 30 wt % or more of diglyceride (DAG, p. 1, para 0009, col. 2, ln. 7). Shiiba discloses an enzyme-treated yolk (p. 2, para 0016) treated with esterase, lipase and/or phospholipase (p. 2, para 0016). Shiiba discloses using between 5 to 20%, and preferably between 8 and 15% of yolk in the oil-in-water emulsion (p. 2, para 0015). Shiiba discloses at least one emulsifier (crystallization

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inhibitor, p. 1, para 0012) selected from sorbitan, polyglycerin, and sucrose fatty acid esters (p. 1, para 0012, ln. 2-3).

Shiiba discloses emulsifier in a range between from 0.5% to 5.0% by weight, and preferably between 0.6 to 3.0% (p. 1, para 0013, ln. 12). In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. MPEP 2144.05. Furthermore, Shiiba prepared examples having 0.6% (p. 4, Table 2, Example 1), 1.0% (p. 4, Table 2, Ex 2 and 4-13), as well as 3.0% (p. 4, Table 2) emulsifier relative to the oil phase.

Regarding the HLB values of the emulsifiers: Examiner notes the HLB scale is between 0 and 20. Shiiba discloses the sorbitan fatty acid has an HLB less than 2.5 (p. 1, para 0013, ln. 10). Shiiba discloses the polyglycerin fatty acid has an HLB less than 3.5 (p. 1, para 0012, ln. 9). Shiiba discloses the sucrose fatty acid has an HLB less than 2 (p. 1, para 0013, ln. 7). In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. MPEP 2144.05. Furthermore, Shiiba prepared examples with the claimed emulsifiers within the claimed ranges.

Emulsifier	HLB (footnotes, p. 4, para 0047)	Example
Sorbitan fatty acid	2.1	4
Polyglycerin fatty acid	2.0	1-3, 6-13

Shiiba does not disclose an antioxidant.

Goto is drawn to an acidic (col. 6, ln. 24) oil-in-water composition (col. 6, ln. 13) comprising diglycerols (col. 2, ln. 63) and phytosterols (col. 6, ln. 20). Goto teaches adding

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antioxidant in the range of 50 to 2000 ppm in the oil composition (col. 4, ln. 66-67). Goto teaches the antioxidant is tocopherol and tocotrienol (col. 5, ln. 3). Goto teaches adding the antioxidant for the purposes of storage stability and flavor stability (col. 4, ln. 67). It would have been obvious to one of ordinary skill in the art at the time of invention to use an antioxidant, as taught in Goto, in the oil-in-water emulsified composition, taught in Shiiba, to obtain an oil-in-water emulsified composition having an antioxidant because the antioxidant improves storage stability and flavor stability (Goto, col. 4, ln. 67).

Shiiba in view of Goto does not expressly recognize the ratio of antioxidant to yolk. However, one of ordinary skill in the art would expect that the limitation is present for several reasons.

First, the prior art suggests range of yolk as disclosed in the Specification, as well as an overlapping range of antioxidant as disclosed and claimed. Shiiba discloses the yolk present between 5% and 20% of the composition (p. 2, para 0015). The Specification discloses the yolk present between 5% and 20% of the composition (Specification, p. 8, ln. 12). Goto discloses between 50 and 2000 ppm antioxidant, which overlaps the disclosed and claimed range of antioxidant. Therefore, one of ordinary skill in the art at the time of invention would expect that the yolk to antioxidant ratio would be present because both constituents, i.e. yolk and antioxidant, are within the disclosed and claimed ranges.

Second, simple calculations suggest the presence of the limitation in the combined references. Shiiba discloses having between 5 and 20% yolk (p. 2, para 0015). Shiiba discloses between 5 and 85% oil (p. 1, para 0011). Goto discloses between 50 and 2000 ppm antioxidant (col. 4, ln. 66-67). The combination of references suggests an antioxidant to yolk percentage of

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between 0.001% ([50 ppm antioxidant * 5% oil]/20% yolk) and 3.4% ([2000 ppm antioxidant * 85% oil]/5% yolk).

Shiiba in view of Goto suggests the ratio as claimed in claim 21 for the reasons discussed above. A calculation of the prior art ranges with respect to the present claims yields: Antioxidant to yolk percentage of between 0.060% ([1800 ppm antioxidant * 5% oil]/15% yolk) and 1.7% ([2000 ppm antioxidant * 85% oil]/10% yolk).

Regarding claim 3, Goto teaches the antioxidant is tocopherol and tocotrienol (col. 5, ln. 3).

Regarding claims 5, 10, 23, and 25, Shiiba does not disclose the composition includes a phytosterol.

Goto is drawn to an acidic (col. 6, ln. 24) oil-in-water composition (col. 6, ln. 13) comprising diglycerols (col. 2, ln. 63) and phytosterols (col. 6, ln. 20). Goto discloses pytosterols reduce cholesterol (col. 1, ln. 15-16). Goto discloses the composition is useful in mayonnaise type products (col. 5, ln. 13). Goto discloses the combination of diglycerides (diacylglycerol, col. 5, ln. 26-27) and phytosterols have a synergistic effect (col. 5, ln. 27-30). It would have been obvious to one of ordinary skill in the art at the time of invention to include phytosterols, as taught in Goto, in the oil in water composition, taught in Shiiba, to obtain oil in water composition having phytosterols. One of ordinary skill in the art would have been motivated to include phytosterols because they reduce cholesterol (col. 1, ln. 15-16).

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9. Claims 6, 15, 17, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiiba et al., USPA 2002/0119239, in view of Goto et al., USPN 6,139,897 as applied to claims 1, 3, 5, and 10 above, and further in view of Koike et al., WO 2002/011552.

Shiiba in view of Goto is relied on as above. Shiiba in view of Goto does not teach an oil-in-water emulsified composition wherein the content of trans-unsaturated fatty acids in the diglyceride is 5% or less.

Koike is drawn to an oil/fat composition having a specific glyceride composition (p. 1, ln. 4-5). Koike teaches a diglyceride with 15 to 90 wt. % of its fatty acid constituents comprising omega 3-unsaturated fatty acids. Koike teaches the content of the trans-unsaturated fatty acid is preferably 5% or less for health reasons (p. 5, ln. 17-18). Koike highlights various negative health aspects of trans-unsaturated fatty acids (p. 2). Koike discloses the composition can be used in oil-in-water compositions like mayonnaise (p. 11, ln. 18). It would have been obvious to one of ordinary skill in the art at the time of invention to use diglycerides with a trans-unsaturated fatty acid content of less than 5%, as taught in Koike, in the oil-in-water emulsion composition, taught in Shiiba in view of Goto, to obtain an the oil-in-water emulsion composition having diglycerides with a trans-unsaturated fatty acid content of less than 5% because diglycerides with 5% and lower trans-unsaturated fatty acids pose less health risks (Koike, p. 2).

Response to Arguments

10. Applicant's arguments filed 9/2/2010 have been fully considered but they are not persuasive.

Applicant argues the prior art's failure to expressly recognize the ratio of antioxidant to yolk is sufficient to overcome the rejections (Remarks, p. 8). Examiner is not persuaded by the argument for several reasons. First, the combination of references suggests the claimed limitation (see rejection above). Second, there is no requirement for prior art to expressly recognize a claimed limitation. "The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. MPEP 2112. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom". MPEP 2144.01. Here, one of ordinary skill in the art would recognize the ratio of antioxidant and yolk to be present for the reasons given in the rejection above.

Applicant argues it is improper to pick and choose random examples to insert an additional ingredient (Remarks, p. 9, first para). Examiner is not persuaded by this argument. There is not a suggestion to pick and choose amongst a combination of various examples to arrive at the claimed invention. Furthermore, Examiner is applying the closest available prior art to demonstrate the level of knowledge to one of ordinary skill in the art.

Applicant argues that Goto fails to disclose an enzyme treated yolk (Remarks, p. 9, first para). However, note that while Goto does not disclose all the features of the present claimed invention, Goto is used as teaching reference, and therefore, it is not necessary for this secondary

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reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, namely the use of antioxidants in oil-in-water compositions, and in combination with the primary reference, discloses the presently claimed invention.

Applicant asserts that one of ordinary skill in the art would not look beyond Shiiba because Shiiba provides no indication of taste inconsistencies (Remarks, p. 9, 2nd para). Examiner is not persuaded by this argument. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues the discovery of a problem can lead to a patentable invention (Remarks, p. 9, last para). However, the prior art recognizes that oxidation occurs in oil-in-water emulsions, like mayonnaise, and suggests antioxidants can be added to improve the product (Goto, col. 4, ln. 67 to col. 5, ln. 1). Contrary to Applicant's assertion (Remarks, p. 10, 2nd full para), Goto expressly recognizes the antioxidant can lead to flavor stability (col. 4, ln. 67).

Applicant argues that a low HLB emulsifier is not commonly used in an oil-in water composition (Remarks, p. 11, last para). Examiner is not persuaded by this argument because Shiiba clearly discloses a low HLB emulsifier in an oil-in-water composition (see rejection above).

Applicant argues unexpected results in the use of the claimed emulsifiers (Remarks, p. 11, 1st para). As set forth in MPEP 716.02(d), whether unexpected results are the result of

unexpectedly improved results or a property not taught by the prior art, “objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support”. In other words, the showing of unexpected results must be reviewed to see if the results occurred over the entire claimed range, *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

Applicants have not provided data to show that the unexpected results do in fact occur over the entire claimed range of antioxidant and emulsifier selected from selected from the group consisting of sorbitan fatty acid ester having an HLB value of 1 to 2.5, polyglycerin fatty acid ester having an HLB value of 1 to 3.5 and sucrose fatty acid ester having an HLB value of 1 to 2, wherein the content of the emulsifier ranges from 0.8 to 2% relative to the oil phase. Applicant relies on a comparison between Examples 2 and 6-8. Examples 6-8 use 0.53% emulsifier, which is less than the presently claimed range of emulsifier. Examples 6-8 use 1942 ppm of antioxidant, which is a single point within the claimed range of 1800 to 3000 ppm. Example 6 uses 0.53% of polyglycerin fatty acid ester having an HLB value of 3.0. Example 7 uses 0.53% of sucrose fatty acid ester having an HLB value of 1.0. Example 8 uses 0.53% of sorbitan fatty acid ester having an HLB value of 2.3. Each exemplary use of antioxidant and emulsifier is a single point within the claimed range. Furthermore, Shiiba also disclosed examples using the claimed emulsifiers within the claimed ranges (see rejection above). Therefore, the data fails to support unexpected results over the claimed range.

Applicant relies on Figure 1 to illustrate unexpected results (Remarks, p. 12). However, Figure 1 illustrates that there is less than a 0.5 change over a five point scale between the "full bodied taste" of example 2 and examples 6-8. The figure illustrates each composition has a full

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bodied taste. Even based on figure 1, it is unclear how much change in full bodied taste is necessary to be an unexpected change. Furthermore, all of the results for examples 1-9 are between 4.0 and a bit over 4.5 (see Figure 1). Therefore, examples 1-9 of the disclosed compositions (including the ones with no emulsifier, Ex 1-5) have a flavor somewhere between evidently good and good.

Applicant alleges that "full-bodied taste" is not a subjective interpretation based on the Specification (Remarks, p. 13, first para). Examiner is not persuaded by this argument. The Specification discloses the organoleptic testing as "handing an unsigned mayonnaise sample to each examiner" at which time the "examiner freely tasted" the product. The 5 point scale is discloses as: 5. evidently good, 4. good, 3. slightly good, 2. slightly bad, 1. bad, and 0. evidently bad (Specification, p. 18). However, Applicant provides no explanation of the meaning of any of the terms or any explanation about the difference between the terms. For example, what is the difference between evidently good and good?

Applicant argues Bailey's Industrial Oil and Fat Products answer the questions concerning subjective taste testing (Remarks, p. 13). However, the Specification when taken in view of Bailey's Industrial Oil fails to indicate the testing was objective or repeatable. First, Bailey's states there are two types of tests product oriented and consumer oriented (p. 414). Baileys discloses the product oriented can be objective and the consumer oriented is subjective. The Specification fails to indicate whether the testing was either one of product- or consumer-oriented. Second, Baileys clearly states "selected and trained panelists" are necessary to obtain objective results (p. 414, last sentence of first para). However, the Specification fails to disclose any training or experience of the panelists. Furthermore, Bailey's discloses "the use of reference

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samples or standards is critical in training and calibration” (p. 420, Section 7). However, the Specification fails to indicate the use of reference samples. Even when viewed in light of Bailey's Industrial Oil and Fat Products, the Specification does not support the contention that the organoleptic testing was objectively performed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER MOORE whose telephone number is (571) 270-7372. The examiner can normally be reached on Monday-Thursday 9:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/WM/

Walter Moore, Examiner AU 1783
9/15/2010

/David R. Sample/

Supervisory Patent Examiner, Art Unit 1783